

US Appl. No. 09/975,418  
AMENDMENT UNDER 37 CFR 1.312

**IN THE CLAIMS:**

1. (currently amended) An inhalable powder comprising 0.04 to 0.8% of tiotropium in admixture with a physiologically acceptable excipient, ~~characterised in that~~ wherein the excipient consists of a mixture of coarser excipient with an average particle size of 15 to 80  $\mu\text{m}$  and finer excipient with an average particle size of 1 to 9  $\mu\text{m}$ , the proportion of the finer excipient constituting 1 to 20% of the total amount of excipient.
2. (currently amended) An inhalable powder according to claim 1, ~~characterised in that~~ wherein the tiotropium is present in the form of the chloride, bromide, iodide, methanesulphonate, paratoluenesulphonate or methyl sulphate thereof.
3. (currently amended) An inhalable powder comprising between 0.048 and 0.96% of tiotropium bromide in admixture with a physiologically acceptable excipient, ~~characterised in that~~ wherein the excipient consists of a mixture of coarser excipient with an average particle size of 15 to 80  $\mu\text{m}$  and finer excipient with an average particle size of 1 to 9  $\mu\text{m}$ , the proportion of the finer excipient constituting 1 to 20% of the total amount of excipient.
4. (currently amended) An inhalable powder comprising between 0.05 and 1% of tiotropium bromide monohydrate in admixture with a physiologically acceptable excipient, ~~characterised in that~~ wherein the excipient consists of a mixture of coarser excipient with an average particle size of

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15 to 80  $\mu\text{m}$  and finer excipient with an average particle size of 1 to 9  $\mu\text{m}$ , the proportion of the finer excipient constituting 1 to 20% of the total amount of excipient.

5. (currently amended) An inhalable powder according to one of claims 1, 2, 3 or 4, characterised ~~in that wherein~~ the excipient consists of a mixture of coarser excipient with an average particle size of 17 to 50  $\mu\text{m}$  and finer excipient with an average particle size of 2 to 8  $\mu\text{m}$ .

6. (currently amended) An inhalable powder according to one of claims 1, 2, 3 or 4, characterised ~~in that wherein~~ the proportion of finer excipient in the total amount of excipient is 3 to 15%.

7. (currently amended) An inhalable powder according to one of claims 1, 2, 3 or 4, characterised ~~in that wherein~~ the tiotropium used has a mean an average particle size of 0.5 to 10  $\mu\text{m}$ .

8. (currently amended) An inhalable powder according to one of claims 1, 2, 3 or 4, characterised ~~in that wherein~~ one or more monosaccharides, disaccharides, oligo- or polysaccharides, polyalcohols, salts thereof, or mixtures thereof are used as the excipients.

9. (currently amended) An inhalable powder according to claim 8, characterised ~~in that wherein~~ glucose, arabinose, lactose, saccharose, maltose, dextrane, sorbitol, mannitol, xylitol, sodium chloride, calcium carbonate or mixtures thereof are used as the excipients.

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10. (currently amended) An inhalable powder according to claim 9, characterised in that wherein glucose or lactose or mixtures thereof are used as the excipients.

11. (original) A process for preparing an inhalable powder according to one of claims 1 to 4, comprising: (a) mixing coarser excipient fractions with finer excipient fractions to obtain an excipient mixture, and (b) mixing the excipient mixture thus obtained with the tiotropium.

12. (original) An inhalable powder prepared by the process according to claim 11.

13. (original) A method of treating a disease that is responsive to the administration of tiotropium, comprising administering to a host in need thereof an inhalable powder according to one of claims 1 to 4 or 12.

14. (original) A method according to claim 13, wherein the disease is asthma or COPD.

15. (original) An inhaler capsule containing an inhalable powder according to one of claims 1 to 4 or 12.

16. (original) An inhaler capsule containing from 3 to 10 mg of inhalable powder according to one of claims 1 to 4 or 12.

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17. (original) An inhalable capsule according to claim 16, containing between 1.2 and 80  $\mu\text{g}$  of tiotropium.
18. (new) An inhalable powder according to claim 4 comprising 0.1 to 0.8% of tiotropium bromide monohydrate.
19. (new) An inhalable powder according to claim 4 comprising 0.2 to 0.5% of tiotropium bromide monohydrate.
20. (new) An inhalable powder according to one of claims 1, 2, 3 or 4, wherein the excipient consists of a mixture of coarser excipient with an average particle size of 20 to 30  $\mu\text{m}$  and finer excipient with an average particle size of 3 to 7  $\mu\text{m}$ .
21. (new) An inhalable powder according to one of claims 1, 2, 3 or 4, wherein the proportion of finer excipient in the total amount of excipient is 5 to 10%.
22. (new) An inhalable powder according to one of claims 1, 2, 3 or 4, wherein the tiotropium used has an average particle size of 1 to 6  $\mu\text{m}$ .
23. (new) An inhalable powder according to one of claims 1, 2, 3 or 4, wherein the tiotropium used has an average particle size of 2 to 5  $\mu\text{m}$ .

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24. (new) An inhalable powder according to claim 10, wherein lactose monohydrate is used as the excipient.
25. (new) An inhalable powder comprising between 0.2 and 0.5% of tiotropium bromide monohydrate in admixture with lactose monohydrate as the physiologically acceptable excipient, wherein the excipient consists of a mixture of coarser excipient with an average particle size of 20 to 30  $\mu\text{m}$  and finer excipient with an average particle size of 3 to 7  $\mu\text{m}$ , the proportion of the finer excipient constituting 5 to 10% of the total amount of excipient.
26. (new) An inhalable capsule containing from 3 to 10 mg of inhalable powder according to claim 25.
27. (new) An inhalable capsule containing from 4 to 6 mg of inhalable powder according to one of claims 1 to 4, 12 or 25.
28. (new) An inhalable capsule according to claim 27, containing between 1.6 and 48  $\mu\text{g}$  of tiotropium.
29. (new) An inhalable capsule according to claim 27, containing between 2 and 60  $\mu\text{g}$  of tiotropium bromide monohydrate.
30. (new) An inhalable capsule according to claim 27, containing between 4 and 48  $\mu\text{g}$  of tiotropium bromide monohydrate.
31. (new) An inhalable capsule according to claim 27, containing between 8 and 30  $\mu\text{g}$  of

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tiotropium bromide monohydrate.